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VB

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
02/0350	10/01/02	BLUDD	R 02/0350-00109

INVENTOR'S ADDRESS NUMBER

R 02/0350-00109

02/0350
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HM12/0916

EXAMINER

DISRING, M

ART UNIT	PAPER NUMBER
1644	15

DATE MAILED:

08/16/03

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/017,524	Applicant(s) Kubo et al
	Examiner Marianne DiBrino	Group Art Unit 1644

Responsive to communication(s) filed on Feb 16, 2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

Claim(s) 6-73 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) _____ is/are rejected.

Claim(s) _____ is/are objected to.

Claims 6-73 are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

1. **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. In view of the Examiner's discussion with BPS Mr. Richard Schwartz, the previous restriction requirement is withdrawn, and the following restriction requirement is set forth.
3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 6, 7, 10-30, 32, 33, 36-48, 50 and 53-64, drawn to a composition comprising an HLA-A1 structural motif-containing peptide, classified in Class 424, subclass 186.1.

II. Claims 31 and 49, drawn to a method for use of a composition comprising a peptide, classified in Class 514, subclasses 2 and 15.

III. Claims 8, 9, 34, 35, 51 and 52, drawn to a composition comprising a nucleic acid, classified in Class 526, subclass 23.5.

IV. Claims 65-67, drawn to a composition comprising an HLA-A3 structural motif-containing peptide, classified in Class 424, subclass 184.1

V. Claims 68-70, drawn to a composition comprising an HLA-A11 structural motif-containing peptide, classified in Class 424, subclass 185.1.

VI. Claims 71-73, drawn to a composition comprising an HLA-A24 structural motif-containing peptide, classified in Class 424, subclass 189.1.

4. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as an antigen for the production of antibodies.

5. Inventions III and II are not related as product and process of use.
6. Inventions III, IV, V, VI and Invention I are not related as products and process of use.

7. Inventions I, II, IV, V and VI are different products.

Nucleic acids (Invention II) and peptides (Inventions I, IV, V and VI) are distinct because their structures are different, i.e., nucleic acids are composed of nucleotides whereas peptides are composed of amino acid residues, and they have different uses, which require non-coextensive searches. The peptides of Inventions I, IV, V and VI are distinct because their structures are different, i.e., they have different motifs and different physico-chemical properties and encompass different sets of nonoverlapping peptides.

Therefore they are patentably distinct.

8. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-VI are not required for any other group from Groups I-VI and Groups I-VI have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

9. Irrespective of whichever Group Applicant elects, Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species of peptide (i.e., a single disclosed species of immunogenic peptide in which all of the amino acid residues are defined, for example, SEQ ID NO: 24) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable and to. Applicant is further required to list the protein from which the peptide is derived.

These species are distinct because their structures are different.

10. This application contains claims directed to the following patentably distinct species of the claimed Invention I wherein the immunogenic peptide:

- A) is linked to a molecule to create a compound; or
- B) is not linked to a molecule to create a compound

If Applicant elects "A", Applicant is further required to elect a specific disclosed species of molecule that is linked to the immunogenic peptide, for example, a T helper epitope, a CTL epitope or a lipid.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the

inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

11. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne DiBrino whose telephone number is (703) 308-0061. The examiner can normally be reached Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Marianne DiBrino

Marianne DiBrino, Ph.D.
Patent Examiner
Group 1640
Technology Center 1600
August 12, 2000

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